K024107

DEC 2 4 2002

Attachment 4

510(k) Summary

This 510(k) summary is submitted in accordance with the requirements in 21 CFR §807.92

Submitted by:	RADI Medical Systems AB Palmbladsgatan 10 SE-754 50 Uppsala, Sweden Phone:(+46) 18161000
Contact Person:	Mats Granlund
Date Prepared:	December 10, 2002
Proprietary Name:	FemoStop® Femoral Compression System
Common Name:	Femoral compression device
Classification Name:	Clamp, DXC
Predicate Devices:	K954669 FemoStop® System K982182 FemoStop®II System K983471 FemoStop®^{PLUS} System K010933 Seal-On Hemostatic Powder Spray K920796 DeRoyal Transparent Film Dressing (Transeal) K962425 Bonopty Coaxial Bone Biopsy System

Description of the Device: The FemoStop®Femoral Compression System consists of an arch with a sterile pneumatic pressure dome attached to an arch, a belt, and a reusable pump with manometer. With this application a sterile hemostatic dressing, HD, is added to the system. The dressing has an active agent made of calcium/sodium salt of micro dispersed oxidized cellulose for topical control of bleeding.

Indication for Use of the Device: FemoStop® Femoral Compression System is indicated for use in the compression of the femoral artery or vein after vessel cannulation, and in ultrasound-guided compression repair of a femoral artery pseudoaneurysm.

Technical Characteristics: The technical characteristics of the actual FemoStop, i.e. are identical to those predicate devices cleared the previous FemoStop applications.

The technical characteristics of the hemostatic dressing - permeable to moisture allowing the skin to breathe but impermeable to water and bacteria, functioning as a bacterial barrier - are substantially equivalent to Transeal, DeRoyal Transparent Film Dressing (K920796) and the technical characteristics of the active substance - induce topical control of bleeding - are substantially equivalent to Seal-On Hemostatic Powder Spray (K010933). The technical characteristics of the

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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RADI Medical Systems AB
c/o Mr. Mats Granlund
Palmbladsgatan 10
SE-754 50 Uppsala, Sweden

Re: K024107
FemoStop® Femoral Compression System
Regulation Number: 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (two)
Product Code: DXC
Dated: December 10, 2002
Received: December 13, 2002

Dear Mr. Granlund:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indication for Use Statement

510(k) Number: K024107

Device Name: FemoStop® Femoral Compression System

Indications for Use: FemoStop® Femoral Compression System is indicated for use in the compression for the femoral artery or vein after vessel cannulation, and in ultrasounded-guided compression repair of a femoral artery pseudoaneurysm

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

for BDZ

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K024107

Prescription Use _____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)